

Project iFoot - Optimising the Treatment of Patients with Diabetic Foot Syndrome with an Intelligent Dressing

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1. Introduction

Diabetes mellitus is one of the world's most serious noncommunicable, chronic diseases and poses a serious public health challenge [1]. An estimated number of 8.5 million Germans currently live with diabetes Type 2 and projections indicate that by 2040, these numbers might increase up to 12.3 million cases [2]. The diabetic foot syndrome (DFS) is a frequent complication of diabetes mellitus and is a collective term for various pathological changes of the foot of people with diabetes mellitus. About 250,000 people in Germany develop a diabetic foot ulcer (DFU) every year, resulting in 13,000 major amputations [3]. The costs of treating diabetic foot syndrome in Germany amount to approximately 2.5 billion euros per year and therefore are of great importance for the health care system [4]. The iFoot research project focuses on an optimized approach to DFS care and has therefore developed an innovative system solution that aims to improve the treatment of DFS by measuring medically relevant values in wound area.

2. Methods

In a prospective, randomized study from February to October 2021 twenty participants between the age of 18 and 85 with a diagnosed form of DFS were included. The primary outcome was time until the wound area was halved; the wound size was documented every 14 days during control visits. Study participants were equipped with a sensor-based intelligent dressing and a commercially available smartwatch. Sensor measurements of pressure, temperature and humidity were recorded near the wound every ten seconds over the entire duration of the study and complemented by the participant's step counts. Participants of the intervention group received audio-visual warning messages via a smartwatch-application in case of exceeding a predefined pressure limit. The aim of this information given to the participants, was to provide a biofeedback in order to

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compensate for the given incomplete sensation in the feet of participant's due to diabetes-related polyneuropathies.

3. Results and Discussion

Participants of the intervention group were able to adjust their behavior by responding to the biofeedback delivered by the smartwatch, enabling them to avoid incorrect pressure load on their feet and resulting in a potentially positive influence on the healing process of the wound. An example is given in figure 1 which shows the pressure measurements of one participant who, after approximately one week during which numerous alarms were triggered, began to consistently reduce the pressure load on his wound. As a result, the circumstances for the healing process of the existing wound seem to have improved and a swift wound closure was detected.

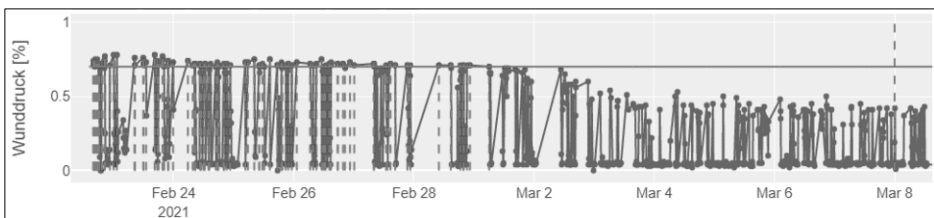


Figure 1. Pressure measurement with alarms shown as dashed lines

Several technical concepts to measure the pressure load on the feet of those who suffer from DFS are published, some are commercially available and mainly serve the purpose of preventing diabetic foot ulcers [5][6]. In distinction to this, the iFoot-system was developed to provide a sensor-based approach to treat DFS with active patient participation.

4. Conclusions

The case-by-case analysis of the recently completed pilot study shows that the use of the iFoot-system is suitable for sensor-based treatment of patients with DFS. In addition to individual case reports, further data evaluations are pending.

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